

Notice of Allowability

Application No.

09/943,857

Examiner

Nashaat T. Nashed, Ph. D.

Applicant(s)

SHAW ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the after-final amendment filed 8/25/05.
2. ☒ The allowed claim(s) is/are 36-57.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

550

Art Unit: 1656

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jimmy Hao on September 28, 2005.

The application has been amended as follows:

Cancel claims 1-35.

Enter new claims 36-57.

- Claim 36. An isolated nucleic acid comprising a mutant DNA encoding a variant *Candida rugosa* lipase having at least 98% identity to SEQ ID NO: 4, wherein the mutant DNA is at least 80% identical to a *Candida rugosa* DNA encoding said lipase which is expressed in *Candida rugosa*, and wherein said mutant DNA has at least 15 CTG codons substituted by codons selected from the group consisting of TCT, TCC, TCA, TCG, AGT, and AGC in the DNA.
- Claim 37. The nucleic acid of claim 36, wherein all CTG codons of said *Candida rugosa* DNA are substituted by codons selected from the group consisting of TCT, TCC, TCA, TCG, AGT, and AGC.
- Claim 38. The nucleic acid of claim 37, wherein the amino acid sequence of the variant *Candida rugosa* lipase is SEQ ID NO: 4.
- Claim 39. The nucleic acid of claim 36, wherein the mutant DNA is at least 85% identical to said *Candida rugosa* DNA.
- Claim 40. The nucleic acid of claim 39, wherein the amino acid sequence of the variant *Candida rugosa* lipase is SEQ ID NO: 4.
- Claim 41. The nucleic acid of claim 36, wherein the mutant DNA is at least 90% identical to the *Candida rugosa* DNA.
- Claim 42. The nucleic acid of claim 41, wherein the amino acid sequence of the variant *Candida rugosa* lipase is SEQ ID NO: 4.
- Claim 43. A microorganism comprising the nucleic acid of claim 36, wherein the microorganism is a bacterium or a yeast.

Art Unit: 1656

- Claim 44. The microorganism of claim 43, wherein the bacterium is *E. coli* and the yeast is *P. pastoris*.
- Claim 45. The microorganism of claim 43, wherein the mutant DNA is at least 85% identical to said *Candida rugosa*.
- Claim 46. The microorganism of claim 45, wherein the bacterium is *E. coli* and the yeast is *P. pastoris*.
- Claim 47. An isolated nucleic acid, comprising a DNA of SEQ ID NO: 3 or a degenerate variant thereof.
- Claim 48. A method for preparing a mutant DNA encoding a *Candida rugosa* variant having at least 98% identity to the amino acid sequence of SEQ ID NO: 4, comprising:
- (a) providing a DNA encoding a variant *Candida rugosa* lipase having at least 98% sequence identity to SEQ ID NO: 4; and
 - (b) conducting PCR amplification by mixing said DNA of (a), a DNA polymerase, a pair of terminal primers for said DNA, and a number of pairs of internal primers encompassing fragments of said DNA of (a), wherein each of the internal primers includes one or more of universal codons and anticodons for serine selected from the group consisting of TCT, TCC, TCA, TCG, AGT, AGC, AGA, GGA, TGA, CGA, ACT, and GCT, in which the universal codons and anticodons substituted for at least 15 CTG codons in the DNA of (a); and each internal primer overlaps with another internal or terminal primer in a manner that a mutant DNA encoding the variant *Candida rugosa* lipase is obtained by amplification.
- Claim 49. The method of claim 48, wherein all codons correspond to CTG codons in said *Candida rugosa* DNA of (a) are substituted by codons selected from the group consisting of TCT, TCC, TCA, TCG, AGT, and AGC.
- Claim 50. The method of claim 48, wherein the amino acid sequence of the variant *Candida rugosa* lipase is SEQ ID NO: 4.
- Claim 51. The method of claim 48, wherein the mutant DNA is SEQ ID NO: 3 or a degenerate variant thereof.
- Claim 52. The nucleic acid of claim 36, wherein the mutant DNA is at least 95% identical to said *Candida rugosa* DNA.
- Claim 53. The nucleic acid of claim 52, wherein the amino acid sequence of

Art Unit: 1656

the variant *Candida rugosa* lipase is SEQ ID NO: 4.

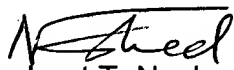
- Claim 54. The nucleic acid of claim 36, where in the variant *Candida rugosa* lipase has 100% identity to SEQ ID NO: 4.
- Claim 55. The microorganism of claim 45, wherein the mutant DNA is at least 90% identical to said *Candida rugosa* DNA.
- Claim 56. The microorganism of claim 55, wherein the mutant DNA is at least 95% identical to said *Candida rugosa* DNA.
- Claim 57. The microorganism of claim 56, wherein wherein the amino acid sequence of the variant *Candida rugosa* lipase is SEQ ID NO: 4.

Claims 36-57 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1656